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3743

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	FLANNIGAN, PAUL J.		
Application No.:	10/719959	Group Art Unit:	3743
Filed:	November 21, 2003	Examiner:	Nihir B. Patel
Title:	RESPIRATORY FACEPIECE AND METHOD OF MAKING A FACEPIECE USING SEPARATE MOLDS		

BRIEF ON APPEAL

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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March 4, 2005
Date

Signed by: Susan M. Dacko

Dear Sir:

This is an appeal from the Office Action mailed on October 4, 2004, finally rejecting claims 1-29.

A Notice of Appeal in this application was mailed on January 4, 2005, and was received in the USPTO on January 4, 2005.

The fee required under 37 CFR § 41.20(b)(2) for filing an appeal brief should be charged to Deposit Account No. 13-3723.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

03/08/2005 HALI11 00000031 133723 10719959
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REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1-29 are pending in this application and are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

Many respirators that are sold today use a thin rigid structural part for attaching filter elements and valves to the mask body. These rigid structural parts are commonly produced through injection molding and are often referred to as a "nosepiece" or "rigid insert". A soft compliant material, which conforms to a person's face, is disposed on or about the rigid structural insert to enable the mask to fit snugly over the wearer's nose and mouth. The use of a rigid insert in conjunction with a soft compliant portion tends to make the mask lighter and more comfortable to wear, particularly when compared to previous masks that had used thick rubber throughout essentially the whole mask body to support the filter cartridges and valves. Examples of masks that use a rigid insert in conjunction with a compliant face-contacting member are shown in U.S. Patent 6,016,804 to Gleason et al., U.S. Patent 5,592,937 to Freund, and U.S. Patent 5,062,421 to Burns et al. For illustrative purposes, the facepiece in the Burns et al. patent is reproduced below:

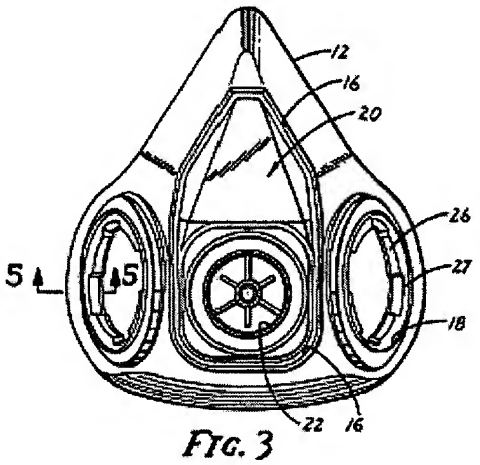
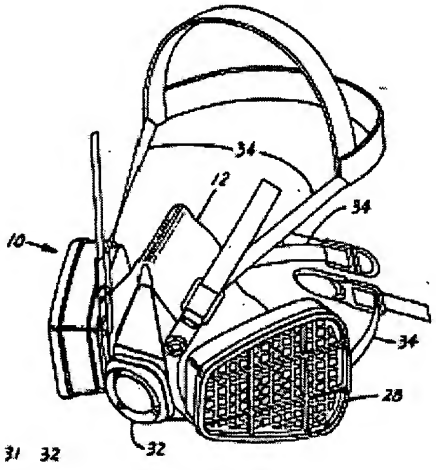


FIG. 3



Burns et al. shows a respiratory mask 10 that has a compliant facepiece 12 and a rigid structural insert 20. The insert 20 has integral fluid communication components 22 and 26. As shown, the rigid structural components that are employed in known mask facepieces regularly incorporate multiple integrated elements that have distinct dimensional tolerance requirements and complex shapes that are customarily formed in molds at relatively great expense.

The control of dimensional tolerance — including actual dimension and conformation of an injected molded part — can be affected by the material used, the cycle time of the part, the mold configuration, and the part design. For a given material and a given part design, the factor that limits production typically is related to the element that has the greatest tolerance requirement. Higher tolerance parts, more-often-than-not, require additional oversight and technical expertise to correctly manufacture.

To properly utilize the efficiency and accuracy of injection-molding technology, designers have sought to encompass as much detail as possible in the molded part so that the whole rigid structural insert can be manufactured in one step. The result therefore often involves complex tooling that is difficult to maintain and operate, especially when used in remote facilities that do not have access to well-trained technical resources. Thus, the higher tolerance requirements for certain portions of the rigid inserts can limit both the design and the production of the whole insert when made using conventional, single-stage, injection-molded technologies. Additionally, when a change to feature in the facepiece insert is needed, such as a different filter mount, a whole new mold must be provided to make the change. That is, a separate mold must be furnished for the whole nosepiece and not simply for a portion of it.

Applicants' invention provides a new method of making a facepiece insert, which method comprises: (a) providing a supporting portion of a facepiece insert; (b) providing a fluid communication component separately from the supporting portion; and (c) securing the fluid communication component to the supporting portion to form the facepiece insert.

The invention also provides a new method of making a respiratory mask body by securing a compliant face-contacting member to the facepiece insert so produced.

The present invention further provides a new facepiece insert that comprises:

(a) a supporting portion of a facepiece insert; and

(b) a fluid communication component that is non-integrally joined to the supporting portion.

In the present invention, the fluid communication components — which commonly are critical tolerance components because they include more complicated and intricate filter attachment mounts and valve seats — are provided in a first step, and, in another step, a supporting portion of a facepiece insert is joined to the fluid communication component. The facepiece insert and its fluid communication components may be made using, for example, injection molding procedures that are carried out as separate operations. The multi-stage operation may address the tolerance mismatch between the insert components. Because the supporting part(s) and the fluid communication part(s) of the insert are separately provided, the inventive method can also support a beneficial distributed manufacturing scheme where fluid communication components can be produced in one location, with the associated expertise and equipment, and the final insert assembly can be carried out in a second location, where the

expertise and associated equipment are lacking. And if a change to the fluid communication component is needed, for example, to allow for a different type of filter attachment, the whole facepiece insert does not need to be reconfigured in the mold. A separate mold need only be provided for the fluid communication component of the facepiece insert (see applicants' specification at pages 2-3).

ISSUES TO BE REVIEWED ON APPEAL

Issue One

Do claims 9, 10, 11, 12, 15, and 20 recite subject matter that is not enabled by the specification?

Issue Two

Applicants claim a method where a fluid communication component, separate from a supporting portion of a facepiece insert, is secured to the supporting portion to create the facepiece insert. A "facepiece insert" is defined in applicants' specification as a rigid element(s) that is fashioned to form part of the mask body but is made separate from the compliant face contacting member to provide structural integrity to the mask body to allow filtration elements and/or valves to be adequately secured thereto. U.S. Patent 6,701,925 to Resnick shows a protective hood respirator 20 that has a mask body 40 that is compliantly adapted to fit over the nose and mouth of the wearer. Resnick's mask body 40 does not include a facepiece insert that has a supporting portion separate from a fluid communication component. Can the Resnick reference nonetheless anticipate the subject mater of claim 1?

Issue Three

A secondary reference, U.S. Patent 5,505,197 to Scholey describes "a mask body 12 [that] is a unitary molded member." Would this patent — despite its failure to also teach or suggest a facepiece insert that has a supporting portion separate from (or non-integral to) a fluid communication component — render obvious the subject matter of claims 3, 4, 16, 21, 22, and 23 in combination with Resnick?

ARGUMENT

Issue One

Claims 9-12, 15, and 20 have been rejected for claiming non-enabled subject matter for the following reason:

> The applicant states that the at least one fluid communication component has a tolerance of less than 0.15 mm, 0.1 mm, and 0.05 mm and the face piece insert has a tolerance of about 0.16 to 0.3 but does not state relative to what which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure.

Applicants have defined the term "tolerance" in the present specification as "the permissible deviation from a specified value of a structural dimension." Applicants submit that a person of ordinary skill certainly can make and use a product that has the tolerances set forth in these claims. As the Board is aware, the burden is on the Examiner to demonstrate otherwise.[1] At the present, the record does not contain any evidence that explains why a person of ordinary skill would not be able to make a facepiece insert that has components with such tolerances. Without such evidence, the 35 USC § 112 rejection cannot be properly sustained.[2]

Issue Two

The rejection of claim 1 under 35 USC § 102(e), as being anticipated by U.S. Patent 6,701,925 to Resnick, cannot be sustained because Resnick does not disclose a mask that has a supporting portion of a facepiece insert. In fact, Resnick does not disclose a facepiece insert — much less an insert that has been made from a supporting portion that is separate from a fluid communication component. Resnick describes a protective hood respirator that has a half-mask cup 40 inside the hood 20:

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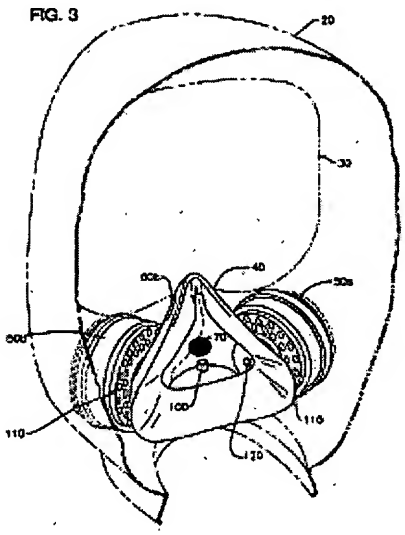
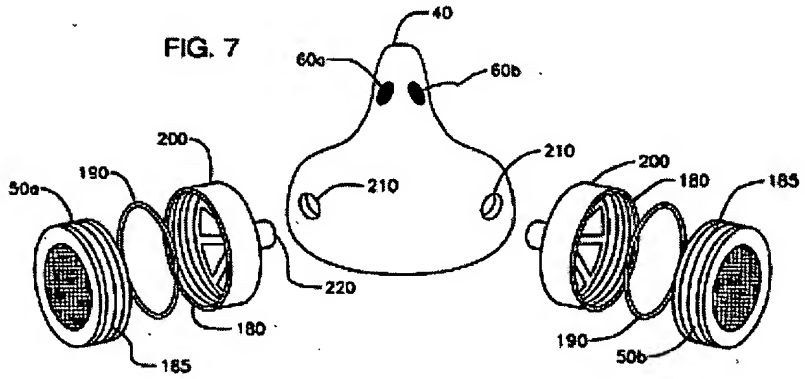
[1] *In re Armbruster*, 512 F.2d 676, 185 USPQ 152, 153 (CCPA 1975); *In re Marzochi*, 439 F.2d 220, 169 USPQ 367, 369-370 (CCPA 1970).

[2] In writing this appeal brief, applicants' attorney noticed that claims 12 and 15 lack the "millimeter" units after the numbers "0.3" and "0.15", respectively. The Examiner has applicants' permission to amend these claims by an Examiner's amendment to eliminate any confusion with respect to the units.





The cup 40 is mechanically, but not fluidically coupled, to the filters 50A-B. Resnick's cup 40 is illustrated as a one-piece cup that does not have a facepiece insert. Because it has a one-piece construction, it is probably made from thick rubber throughout essentially the whole mask body. Please see the first paragraph in the background section of the present specification:

> Many respirators that are sold today use a thin rigid structural part for attaching filter elements and valves to the mask body. These rigid structural parts are commonly produced through injection molding and are often referred to as a "nosepiece" or "rigid insert". A soft compliant material, which conforms to a person's face, is disposed on or about the rigid structural insert to enable the mask to fit snugly over the wearer's nose and mouth. **The use of a rigid insert in conjunction with a soft compliant portion tends to make the mask lighter and more comfortable to wear, particularly when compared to previous masks that had used thick rubber throughout essentially the whole mask body to support the filter cartridges and valves.** Examples of masks that use a rigid insert in conjunction with a compliant face-contacting member are shown in U.S.

Patent 6,016,804 to Gleason et al., U.S. Patent 5,592,937 to Freund, and U.S. Patent 5,062,421 to Burns et al.

Because applicants' invention is directed to the use of a rigid insert — which in conjunction with a compliant face contacting member would form a mask body — and Resnick only describes a one-piece mask body, Resnick does not disclose applicants' invention so as to anticipate it under 35 USC § 102.

Issue Three

As indicated above, Resnick does not teach or suggest making a mask body that has a rigid facepiece insert. Nor does Resnick teach making a mask from a supporting portion that is separate from its fluid communication component. Scholey also adds little or nothing to what is lacking in Resnick. Scholey describes "a mask body 12 [that] is a unitary molded member...."[3] Scholey does, however, indicate that the mask body could be manufactured in different pieces and assembled together to form a unitary member at column 3, lines 20-22. But this disclosure, does not suggest providing a fluid communication component that is non-integrally joined to the supporting portion of a facepiece insert. Masks that have been made from separate pieces, subsequently assembled together, have been known for years. Please see the first paragraph in applicants' specification, reproduced above.

In applicants' invention, the fluid communication components — which commonly are critical tolerance components because they include more complicated and intricate filter attachment mounts and valve seats — are provided in a first step, and, in another step, a supporting portion of a facepiece insert is joined to the fluid communication component. The facepiece insert and its fluid communication components may be made using, for example, injection molding procedures that are carried out as separate operations. The multi-stage operation may address the tolerance mismatch between the insert components. Because the supporting part(s) and the fluid communication part(s) of the insert are separately provided, the inventive method can also support a beneficial distributed manufacturing scheme where fluid communication components can be produced in one location, with the associated expertise and equipment, and the final insert assembly can be carried out in a second location, where the expertise and associated equipment are lacking. And if a change to the fluid communication

[3] See Scholey at column 3, line 16.

component is needed, for example, to allow for a different type of filter attachment, the whole facepiece insert does not need to be reconfigured in the mold. A separate mold need only be provided for the fluid communication component of the facepiece insert.

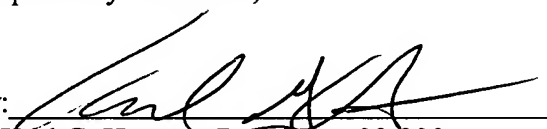
Resnick and Scholey fail to teach or suggest the basic features of applicants' invention and the benefits that are provided by the features. As such, Resnick and Scholey would not have rendered applicants' invention obvious to a person of ordinary skill, whether taken alone or in combination. Accordingly, the rejection under 35 USC § 103 should be withdrawn.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application under 35 USC §§§ 102, 103, and 112.. Please reverse the decision below.

Respectfully submitted,

March 4, 2005
Date

By: 
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Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833

CLAIMS APPENDIX

1. (original) A method of making a facepiece insert that has at least one fluid communication component, which method comprises:

(a) providing at least one supporting portion of a facepiece insert;

(b) providing at least one fluid communication component separately from the supporting portion of the facepiece insert; and

(c) securing the at least one fluid communication component to the at least one supporting portion.

2. (original) A method of making a respiratory mask body, which method comprises the steps of claim 1 and further comprises:

(d) securing a compliant face-contacting member to the facepiece insert.

3. (original) A method of making a respiratory mask, which method comprises the steps of claim 2 and further comprises:

(e) securing a harness to the mask body.

4. (original) The method of claim 3, further comprising providing at least one filter cartridge that is capable of being attached to the at least one fluid communication component.

5. (original) The method of claim 1, wherein the at least one fluid communication component is a critical tolerance component.

6. (original) The method of claim 2, wherein the at least one fluid communication component is a critical tolerance component.

7. (original) The method of claim 3, wherein the at least one fluid communication component is a critical tolerance component.

8. (original) The method of claim 1, wherein the at least one supporting portion of the facepiece insert and the at least one fluid communication component are made from similar polymeric materials and are fused together.

9. (original) The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.15 millimeters.

10. (original) The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.1 millimeters.

11. (original) The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.05 millimeters.

12. (original) The method of claim 1, wherein the supporting portion of the facepiece insert has a tolerance of about 0.16 to 0.3.

13. (original) A facepiece insert that comprises:

(a) a supporting portion; and

(b) a fluid communication component that is non-integrally joined to the supporting portion.

14. (original) A respiratory mask body that comprises the facepiece insert of claim 13, and further comprises a compliant face contacting member that is non-integrally joined to the supporting portion of the facepiece insert.

15. (original) The respiratory mask body of claim 14, wherein the fluid communication component has a tolerance of 0.15 or less, and wherein the supporting portion has a tolerance of about 0.16 mm or greater.

16. (original) A respiratory mask, that comprises the mask body of claim 14, and further includes a harness for supporting the mask body over a person's nose and mouth.

17. (original) A respiratory mask, that comprises the mask body of claim 14, and further includes a filter cartridge for supporting the mask body over a person's nose and mouth.

18. (original) The respiratory mask of claim 16, wherein the fluid communication component comprises part of an inhalation valve.

19. (original) The respiratory mask of claim 16, wherein the fluid communication component comprises part of an exhalation valve.

20. (original) A respiratory mask of claim 16, wherein the fluid communication component has a tolerance of 0.15 or less, and wherein the supporting portion has a tolerance of about 0.16 to 0.3 mm.

21. (original) The respiratory mask of claim 16, wherein the supporting portion and the fluid communication component are fused together.

22. (original) A respiratory mask that comprises:

(A) a mask body that includes:

(1) a facepiece insert that includes:

(a) a supporting portion;

(b) at least one fluid communication component that is non-integrally joined to the supporting portion and that is a critical tolerance component; and

(2) a compliant face-contacting member that is non-integrally joined to the supporting portion of the facepiece insert; and

(B) a harness for supporting the mask body at least over a person's nose and mouth.

23. (original) The respiratory mask of claim 23, further comprising at least one filter cartridge that is secured to the mask body at a location where the fluid communication component resides.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.